



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,483	03/22/2004	Hans-Juergen Kuhr	WP 21667 US	2791

23690 7590 11/15/2006

Roche Diagnostics OPERATIONS Inc.
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER

FOSTER, MARLEE CHRISTINE

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,483

Applicant(s)

KUHR ET AL.

Examiner

Marlee C. Foster

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/22/2004; 7/6/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Germany on 20 March 2003. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Levin et al. (U.S. Patent 6,168,606). Levin et al. disclose, in the figures, a lancing aid comprising a housing with a holding element that interacts with the lancing aid holding element when the lancet is positioned in the housing. The needle of the lancing system has a tip connected to the body. The needle body comprising a protective portion that can be moved relative to the needle and surrounds the tip in a first position, as shown in figure 7. The protective portion of the needle (80) and the needle tip are arranged relative to one another in a second position (shown as 46 in figure 7). An opening in the housing allows the needle to emerge from the lancing system and penetrate the skin. A drive mechanism is transferred from a resting position to a lancing position. A blocking mechanism, as indicated by 70, is an interaction with the housing that prevents the

Art Unit: 3731

ejection of the lancet system from the housing. The holding element of the housing prevents the holding element of the lancet system from being reinserted into the housing, and preventing the reuse of the system. Regarding claim 2, Levin et al. disclose a plastic fiber connection as one of the holding elements of the housing that prevents the reinsertion and reuse of the lancet system in the housing (col. 3, lines 18-29). Regarding claims 5 and 8, the pull-tab (90) and the safety cap (80) located on the needle prevent a compressive force from the pull-tab to allow the drive spring to recock the needle. Additionally, the interactions of the vertical projections (71 and 72) and the lugs (73 and 74) inside the housing prevent the needle from firing prematurely.

4. Claims 12, 13, 14, 16, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruppert (U.S. Patent 5,152,775). Ruppert discloses a lancet system comprising a plurality of needles with a tip, a needle body with a holding element that interacts with the holding element of the lancing aid. The needle body is connected with the needle in such a manner that at least one protective portion partially surrounds the needle tip in the first and second position (figure 2, 38). The protective portion of the needle body and needle tip are shown in figure 7 to be spatially separated from one another such that the needle tip is releasable by the protective portion of the needle body. The blocking mechanism in the needle body is actuated by an interaction with the lancing aid and changes the needle body such that after ejection of the lancet system, the holding element is prevented from interacting with the holding element of the lancing aid when reinserted (col. 5, lines 4- 40). Regarding claim 14, Ruppert discloses the protective portion of the needle body is a storage container for many needles (see

Art Unit: 3731

figures 1a-1c). Regarding claims 16 and 17, part of the blocking mechanism of Ruppert's device includes a stripping mechanism (40) that exposes the tip of the needle during advancing, and destroys the protective holding element on the needle (col. 5, lines 28- 33). This holding element is shaped to the needle itself until it is removed by the stripping mechanism. By removing the outer protective holding layer, the shape of the Ruppert's needle is changed as it advances in the device, and stripping off the outer protective layer reduces the area of the needle.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 3731

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (U.S. Patent 6,168,606) in view of Morita (U.S. Patent 5,314,442).

Levin et al. disclose a single-use lancing device with a needle and tip, pre-cocked with a safety cap to prevent accidental firing and puncture. Levin et al. fail to disclose more than one specific and independently acting holding elements within the lancet system and housing. Morita teaches a lancing device with many holding elements, shown as 107, 122, and 113 in figure 5. Morita teaches the first and second lockable means are provided to retain the needle within the housing, and prevent it from extending too far past the opening of the housing. Regarding claim 6, the blocking mechanism separates the holding members, or lugs, when the needle assembly is inserted in the device (col. 4, lines 33-44). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Levin et al. to include more holding elements or lockable means to secure the needle within the housing and prevent firing through the opening.

9. Regarding claim 4, Levin et al. disclose a needle that is movable between a cocked and striking position within the housing. However, Levin et al. fail to disclose a needle moveable into a non-firing position. Morita teaches a similar lancing device with the needle moveable into a neutral position to while the lockable arms are recovering to

Art Unit: 3731

an undeformed state (col. 13, lines 42-46). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Levin et al. in view of the teachings of Morita to maintain the needle assembly in a neutral position so that it is further prevented from accidental firing and causing a needlestick injury to the user.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (U.S. Patent 6,168,606) in view of Ruppert (U.S. Patent 5,152,775). Levin et al. disclose the device substantially as claimed, but are silent with respect to a blocking mechanism that activates when the lancet system is ejected from the housing. Ruppert teaches a slide member that actuates one needle, then is moved to a second position to guide another needle assembly, ensuring that the used needle does not re-enter the assembly (col. 2, line 65- col. 3, line 33). This important feature in the lancing assembly prevents a contaminated needle from entering the assembly and possibly infecting a user. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Levin et al. with the feature of Ruppert to prevent contaminated needles from re-entering the lancing system.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (U.S. Patent 6,168,606) in view of Strong et al. (U.S. Patent 5,423,847). Levin et al. disclose the invention substantially as claimed, but fail to disclose a blocking mechanism actuated during a lancing operation. Strong et al. teach an interlocking mechanism with angulated slots programmed to sense the ejection of a lancet and whether the lancet that is in the injector is used or not (col. 3, lines 55-65). This

Art Unit: 3731

prevents accidental misuse or cross-contamination between patients. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include an interlocking mechanism in the device of Levin et al. to prevent accidental misuse of contaminated needles.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (U.S. Patent 6,168,606) in view of Schraga (U.S. Patent 5,797,942).

Levin et al. disclose a lancing device, but fail to disclose the protective portion of the needle body transferred to the first position, or resting position, during ejection.

Schraga teaches the protective part of the needle transferred to a resting, or withdrawn position, during an ejection phase of the lancing assembly, as shown in figures 5A and 5B. This features acts to prevent cross contamination of the needles before and after ejection of the assembly. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to enable the protective part of the needle to move during ejection in the device of Levin et al. to prevent accidental misuse or cross-contamination of needles.

13. Claims 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruppert (U.S. Patent 5,152,775) in view of Kuhr et al. (U.S. Patent 6,783,537). Ruppert fail to disclose a lancing device wherein part of the needle body comprises a blocking mechanism, and the blocking mechanism of the needle has a preset breaking point that breaks when it is ejected from the lancet system. The blocking mechanism of Kuhr et al. is a protective sheath (14) over the needle, which acts to enlarge the area of the needle. This protective sheath has a predetermined

Art Unit: 3731

breaking point so that the protective sheath may be cleanly removed from the needle (col. 6, lines 22-26). This blocking mechanism is actuated independently of the protective portion of the needle body. The protective sheath is preferable in devices with many needles, stored in a magazine, and serves to protect the lancet tip from bending or contamination, as well as serving to protect the user (col. 6, lines 60-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a protective sheath that is easily removable on the device of Ruppert.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Teo et al. (US 2002/0128608) and Crossman (U.S. Patent 6,719,771) disclose similar devices of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marlee C. Foster

MCF

[Signature]
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/11/00